UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

A.O.A., *et al.*,	)	
	)	Case No. 4:11-cv-00044-CDP
Plaintiffs,	)	(CONSOLIDATED)
	)	
vs.	)	
	)	
THE DOE RUN RESOURCES	)	
CORPORATION, *et al.*,	)	
	)	
Defendants.	)	

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE PROFFERED OPINION TESTIMONY OF PLAINTIFFS' EXPERT WITNESS DAVID L. MACINTOSH, Sc.D., CIH, UNDER RULE 702 AND *DAUBERT*

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I.   INTRODUCTION

Dr. MacIntosh's claimed area of expertise is exposure assessment. In this litigation, he has created a series of statistical models that purport to predict Plaintiffs' blood lead levels ("BLLs") and to attribute a portion of those BLLs to Doe Run Peru's ("DRP") operation of the La Oroya Complex (the "Complex"). Each of his models suffers from fatal flaws—so much so that Dr. MacIntosh has "supplemented," "refined," or corrected his models numerous times. Indeed, Dr. MacIntosh has submitted no less than *eight* reports, addenda, or supplemental reports,[1] many of which completely revised the prior versions of his models and their assumptions in response to Defendants' well-founded criticisms.[2] But despite his repeated revisions, the flaws remain.

The original three models that Dr. MacIntosh generated are:

- A community-average blood lead model which compares BLLs for children 0-7 years of age to lead in air in the La Oroya community between 1999-2007 (Fig. 9.3 in Ex. A, MacIntosh 02/18/19 Rep.);

- A predictive model for individual children in relation to 90-day average air lead concentrations at the closest air monitoring station (Fig. 9.4 in Ex. A, MacIntosh 02/18/19 Rep.); and

- An allocation model to calculate the percentage of BLLs allegedly attributable to DRP's operation of the Complex (Fig. 9.7 in Ex. A, MacIntosh 02/18/19 Rep.).

The principal underlying assumption—and what drove the design of all three models— was Dr. MacIntosh's unsupported assumption that air lead is the single factor driving up BLLs in

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[1] Dr. MacIntosh's reports are: MacIntosh Expert Report 02/18/19 (Ex. A); MacIntosh First Supplemental Report 02/18/19 (produced on 05/01/19) (Ex. B); MacIntosh Second Supplemental Report 06/10/19 (Ex. C); Letter to Counsel with Additional Corrections & Revisions 06/10/19 (Ex. D); MacIntosh Rebuttal Expert Report 06/22/20 (Ex. E); MacIntosh Addendum to Rebuttal Report 08/04/20 (Ex. F); MacIntosh Third Supplemental Expert Report 12/01/20 (Ex. G); MacIntosh Fourth Supplemental Expert Report 05/28/21 (Ex. H).

[2] Many of the revisions occurred after his depositions. Dr. MacIntosh has been deposed three times, on May 14, 2019, on August 5, 2020, and on June 23, 2021. Relevant pages of his depositions are attached as Ex. I (MacIntosh 05/14/19 Dep.) and Ex. J (MacIntosh 08/05/20 Dep.).

the La Oroya community generally, and in these Plaintiffs specifically. Contrary to well-established exposure assessment methodology, the authoritative scientific literature, and guidelines issued by the U.S. Environmental Protection Agency ("EPA"), Dr. MacIntosh's models ignore all other significant sources of lead in the La Oroya area, including the widespread contamination from 70+ years of pre-DRP operations of the Complex—contamination that remains in the area because the Government of Peru failed to remediate the pervasive soil contamination to which residents continue to be exposed. The problem with this assumption is that even Dr. MacIntosh's own models prove that air lead alone is not a good predictor of BLLs. Under his community model (Fig. 9.3), even when air lead emissions are zero, the expected average BLL is 13 µg/dL; under his predictive model (Fig. 9.4), the number is close to 25 µg/dL. In other words, even if DRP had no air lead emissions whatsoever, the average BLLs in La Oroya's children would still have been higher than the U.S. Centers for Disease Control and Prevention's ("CDC") level of concern for lead when DRP acquired the Complex.[3] Further, Dr. MacIntosh's predictive model fails to confirm the "strong" relationship that Dr. MacIntosh contends exists between current air lead emissions and BLLs, showing that only about 23% of the variability in BLLs is related to air lead—meaning *that the vast majority of the variability in BLLs (77%) is related to other sources*. *See* Ex. L, MacIntosh 5/14/19 Dep. Ex. 12; Ex. M, Report of Teresa Bowers ("Bowers Rep.") at 15 (Dr. MacIntosh's model has poor predictive capability); Ex. N, Report of Shahrokh Rouhani ("Rouhani Rep.") at 9 ("The low R-squared values … point to the poor reliability of Dr. MacIntosh's predictive model."). Further, the model he chose to use—a single slope factor model—is not as robust as biokinetic models such as the Integrated Exposure Uptake Biokinetic

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[3] When DRP acquired the Complex in 1997, CDC's level of concern for lead was 10 µg/dL. In 2012, the CDC adopted a "reference value" of 5 µg/dL. Ex. K, Report of Barbara Beck ("Beck Rep.") at 9.

Model ("IEUBK"), which considers numerous potential environmental sources of lead. At least one court has excluded Dr. MacIntosh's testimony because he selected a weaker exposure assessment model. *See Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 797 (Del. 2006).

Even more significantly, Dr. MacIntosh uses his predictive model to predict BLLs for individual Plaintiffs at specific points in time. While Dr. MacIntosh is correct that slope factor models may be used for predicting expected or average ***community*** BLLs, these models cannot be used to estimate BLLs for ***individuals***. In fact, the EPA has explicitly stated that these models cannot produce estimates for any given child, because of the inherent differences between children and their exposures. Ex. M, Bowers Rep. at 16-17 (citing EPA, *Validation Strategy for the Integrated Exposure Uptake Biokinetic Model for Lead in Children* (1994) ("EPA *Validation*"), available at https://bit.ly/EPA-Valid.

Dr. MacIntosh's allocation model (Fig. 9.7) fares no better. Dr. MacIntosh bases this model on improper valuations of background BLLs in La Oroya as well as incorrect assumptions of the blood lead half-life. In fact, he made so many errors in this model and revised it so many times that it is unclear which version he intends to finally testify about.[4]

Dr. MacIntosh utilized fundamentally unscientific processes and unfounded assumptions contrary to existing literature and the generally accepted consensus of the relevant scientific community. His opinions are unreliable and should be excluded in their entirety under FED. R. EVID. 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and its progeny.

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[4] In his Addendum report, Plaintiffs' expert Howard Hu calls into question the reliability of Dr. MacIntosh's updates to his allocation model, and chooses to reject Dr. MacIntosh's revised version in reaching his own opinions about the "adverse health consequences that are attributable" to DRP. Ex. O, Hu Addendum 08/09/21 at 2-3.

II.   LEGAL STANDARD

Under *Daubert* and Federal Rule of Evidence 702, a federal district court has a **duty** to act as a "gatekeeper," ensuring that only scientifically reliable and relevant expert evidence is presented to the jury. *Daubert*, 509 U.S. at 589. Rule 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if":

(a)   the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b)   the testimony is based on sufficient facts or data;

(c)   the testimony is the product of reliable principles and methods; and

(d)   the expert has reliably applied the principles and methods to the facts of the case.

In *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir. 2014), the court explained that "[t]he screening requirement of Rule 702 has been boiled down to a three-part test":

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Id. at 561. "The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence." *Redd v. Depuy Orthopaedics*, 700 F. App'x 551, 554 (8th Cir. 2017).

"To show that the expert testimony is relevant, the proponent must show that the reasoning or methodology in question is applied properly to the facts in issue." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006); *see Daubert*, 509 U.S. at 591-92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."); *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 687 (8th Cir. 2001) (court must consider "whether the proposed expert sufficiently connected the proposed testimony with the

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facts of the case"). "Failure to show the reliability of each step in an expert's methodology is fatal under *Daubert*." *In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007). Moreover, "[e]xpert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis." *J.B. Hunt Transp., Inc. v. GMC*, 243 F.3d 441, 444 (8th Cir. 2001).

In *Daubert*, "the Supreme Court set forth four factors to guide district courts in resolving admissibility questions: whether the expert's methodology has been tested, has been subjected to peer review, has a known or knowable error rate, and is generally accepted in the scientific community." *Kirk v. Schaeffler Grp. USA, Inc.*, 887 F.3d 376, 391 (8th Cir. 2018). "*Daubert*'s progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Lauzon*, 270 F.3d at 687. In weighing these factors, the court properly exercises its gatekeeping function by "separat[ing] expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

Under this standard, the Court should exclude Dr. MacIntosh's proposed expert testimony.

III. **PLAINTIFFS HAVE FAILED TO MEET THEIR BURDEN UNDER *DAUBERT* AND RULE 702 TO SHOW THAT DR. MACINTOSH'S TESTIMONY IS RELIABLE AND ADMISSIBLE**

A. **Dr. MacIntosh's Predictions of Plaintiffs' Blood Lead Levels Are Unreliable**

Dr. MacIntosh purports to create a model that can "predict" these Plaintiffs' BLLs at various points in time based on contemporary air lead emissions. Ex. C, MacIntosh 6/10/19 Rep. at 18. However, his predictive model and the resulting "estimated" BLLs are inherently

unreliable.[5]

1. Dr. MacIntosh's methodology to "estimate" individual blood lead levels is not generally accepted by the relevant scientific community

Dr. MacIntosh improperly uses his predictive model to calculate BLLs for individuals even though this is contrary to well established exposure assessment methodology. As the EPA has repeatedly stated, "prediction of a specific child's measured blood lead level is not one of the model's intended or valid uses." EPA *Validation* at 6. Individual BLL predictions are inherently unreliable because there is a great degree of variability between individuals, even when exposed to identical levels of lead in air and/or soil.

The EPA, while discussing the proper use of models to predict community BLLs, has expressly stated that such models should not be used "to reproduce the observed blood lead level for any specific child, because of the practical limitations of exposure characterizations." *Id*. One of the key "practical limitations" is a model's inability to account for individual variability between children. *Id*. This is because variability in BLLs depends on a variety of behavioral and biological factors that impact the amount of lead an individual child will ingest, biokinetics, or the amount of lead the body ultimately absorbs, such as hand-to-mouth behavior, time spent outdoors vs. indoors, house cleaning habits, weather and seasons, and timing of exposure relative to eating. Ex. M, Bowers Rep. at 16-17; EPA *Validation* at 14-15. These individual factors significantly impact variability in BLLs across children in the same community exposed to the same environmental levels. Ex. M, Bowers Rep. at 9; EPA, *Exposure Factors Handbook* (2011), available at https://bit.ly/EPA-EFH. "Most importantly, the Model is not a substitute for medical evaluation of

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[5] This is particularly significant for the six Plaintiffs who have no measured BLLs and thus cannot prove actual exposure to lead. *See* Defendants' Motion for Summary Judgment, filed concurrently herewith.

an individual child." EPA *Validation* at 6. No model that considers only environmental lead concentrations in relation to BLLs can account for all or even most of the individual factors that would cause one child to have a higher BLL than another child at the same time and in the same community. As Figure 9.4 from Dr. MacIntosh's report below shows, BLLs vary wildly at identical air concentrations. Indeed, Dr. MacIntosh's own predictive model demonstrates that "[a]t any particular air lead concentration, such as 2.57 µg/m^3, blood lead levels range from 5.8 to 86.6 µg/dL, representing a substantial amount of variability in the response of individual children to a specific air lead concentration." Ex. M, Bowers Rep. at 17. The same is true for any air lead concentration in Dr. MacIntosh's Figure 9.4, in which the 95% confidence interval for BLLs in 2-year-olds varies by nearly 40%. *Id.* Thus, even if Dr. MacIntosh's predictive model were based on sound methodology—which it is not—it cannot be reliably used to "estimate" BLLs for the individual Plaintiffs.
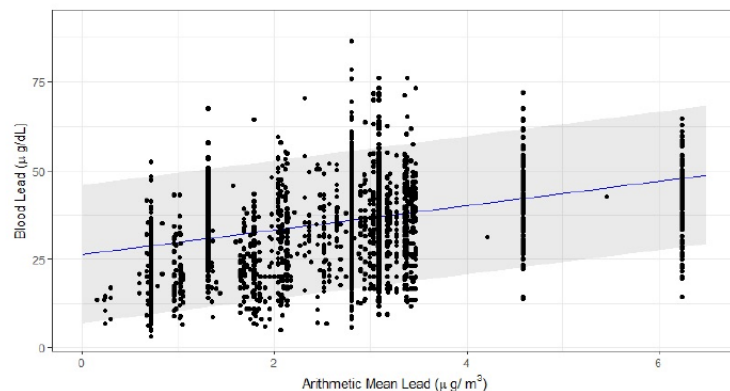
Figure 9.4. Plot of blood lead measured for individual children 0 – 7 years of age in La Oroya in relation to the 90-day average air lead concentration preceding the date of each child's blood lead test. The blue line represents the line of best fit and the shaded band represents the 95% confidence interval for a 2-year old child in La Oroya Antigua.

2.   **Dr. MacIntosh's methodology for developing his predictive model is unreliable**

In his predictive model, Dr. MacIntosh used BLL measurements from individuals in La Oroya and the average air lead concentrations 90 days before the BLL measurement was taken, as measured by the monitoring station closest to the community where the individual was located.

Ex. C, MacIntosh 6/10/19 Rep. at 22. Dr. MacIntosh uses an unreliable methodology in generating his predictive model.

a. Dr. MacIntosh erroneously selected an inferior model where more robust models were available

Dr. MacIntosh's testimony has been excluded in a prior case, where the court found that his methodology was unreliable because he could not sufficiently explain why he "rel[ied] exclusively upon [an inferior] model and … ignore[d] or discard[ed] 'more favorable' methodologies." *Bowen*, 906 A.2d at 797.[6] Here, Dr. MacIntosh has once again opted for an inferior statistical model despite the availability of other, more robust models such as the IEUBK. Therefore, his opinions in this case should be excluded as unreliable.

(i) The single factor slope regression model is inferior

For his predictive model, Dr. MacIntosh selected a slope factor model that considers only air lead data, even though he admits that "[b]iokinetic models for lead are generally accepted and widely used in the field of public health." Ex. C, MacIntosh 6/10/19 Rep. at 15; *see also* Ex. E, MacIntosh 6/22/20 Rep. at 10. Biokinetic models such as the IEUBK can account for the influence of multiple exposure pathways on BLLs, "including air, dust, soil, water, and food, as well as information on contact that children have with those media, e.g., how much air children breathe and how much soil and dust children ingest." Ex. C, MacIntosh 6/10/19 Rep. at 15. Single factor slope regression models, on the other hand, only analyze the relationship between blood lead and one exposure medium. *Id.* at 15–16. Dr. MacIntosh ignores EPA's warning regarding the use of a model with only one predictor variable: "Slope factor models are ***highly simplified representations*** of empirically based regression models in which the slope parameter represents

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[6] Delaware's evidentiary rules regarding expert testimony parallel the Federal Rules of Evidence. *See Bowen*, 906 A.2d at 794–95.

the change in blood [lead] concentration projected to occur in association with a change in [lead] intake or uptake." EPA, *Integrated Science Assessment for Lead*, 3-135 (2013) (emphasis added), available at https://bit.ly/EPA-ISA.

Dr. MacIntosh's selection of a slope factor model is even more problematic because he concedes that "[c]hildhood lead exposure is a multivariate problem with the effects of multiple sources of lead being mediated by multiple sociodemographic factors." Ex. J, MacIntosh 8/5/20 Dep. at 36:4–12. His single slope factor model not only fails to account for the sociodemographic factors that might differ from one child to the next, but also for any sources of exposure other than contemporary air lead emissions. Even though he acknowledges the importance of dust and soil as sources of lead in his rebuttal report, he still insists that air lead is the "best predictor" of blood lead and serves as a proxy for all sources. Ex. E, MacIntosh 6/22/20 Rep. at 5. He assumes— without support and contrary to the actual conditions in the region—that all lead in soil and dust is attributable to air emissions from DRP.

By analyzing only air lead without considering other available data, Dr. MacIntosh predisposes his model to show that air lead is the primary driver of BLLs, even if it is not. But his model actually shows that contemporary air lead emissions are poor predictors and are not strongly correlated with individual BLLs. Even his model shows that he is ignoring other more significant sources of lead exposure that may impact BLLs. An expert's failure to consider all available data and "to reassess his opinion in light of actual test results is 'the antithesis of good science.'" *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 669 F. Supp. 2d 514, 523 (M.D. Pa. 2009) (quoting *In Re TMI Litig.*, 192 F.3d 613, 676 (3d Cir. 1999)).

(ii)   **The superior biokinetic model was a feasible option**

Dr. MacIntosh fails to justify his use of the slope factor model over more robust models, including biokinetic models. Dr. MacIntosh acknowledges that soil and dust ingestion are the most

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significant sources of lead exposure. Ex. E, MacIntosh 6/22/20 Rep. at 6; Ex. I, MacIntosh 5/14/19 Dep. at 116:9–14 ("The ingestion of dust is likely to be the predominant pathway contributing to the blood leads observed"). But he still opines that air lead is the "*best* predictor of BLL in La Oroya." Ex. E, MacIntosh 6/22/20 Rep. at 5 (emphasis in original). He supports his opinion by arguing that (1) there is insufficient dust or soil lead data available and (2) air lead is a sufficient proxy for dust and soil lead. Neither statement is correct.

First, there is a great deal of data available from other exposure sources, all of which was available to him. Ex. C, MacIntosh 6/10/19 Rep. at 8–9, A-6. Indeed, by Dr. MacIntosh's own admission, "a tremendous amount of environmental measurement data exists for this area."[7] Ex. I, MacIntosh 5/14/19 Dep. at 135:22–24. Dr. MacIntosh provides no scientific support for his opinion that he can only use soil or dust data from a particular year to run his model. He did not do any kind of soil mixing analysis or evaluate the validity of the soil data, which is plentiful. Ex. J, MacIntosh 8/5/20 Dep. at 54:25–55:3. Rather, he made no attempt to evaluate whether he could use the existing soil data. Dr. MacIntosh attempts to justify his failure to take soil lead into account by stating that there is "not much soil" in La Oroya. *Id.* at 55:16-18. However, this is untrue. Ex. P, Report of John Connor ("Connor Rep.") at 38-39, 161-62 (bare and exposed soil is plentiful in La Oroya, representing "a nearly infinite supply of lead-contaminated dust that falls and will continue to fall upon the town" until the Peruvian government implements an effective soil remediation program). Moreover, Dr. MacIntosh admits that he could have used a more robust biokinetic model by taking steps to model lead exposure through other pathways. Ex. I, MacIntosh 5/14/19 Dep. at 136:1–21. Such modeling is not even necessary: levels of lead in soil do not change

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[7] There are hundreds of available sample results from Integral Consulting's sampling of soils, dust, food, and water in the area. Integral performed a site-specific integrated stochastic exposure (ISE) model that considered all of the available data. *See* Ex. M, Bowers Rpt. at 11.

so dramatically that values from other years could not be used. Ex. J, MacIntosh 8/5/20 Dep. at 54:17–24 ("Q: [I]s it your opinion that lead in soil degrades over time? A: No.").

Second, Dr. Dr. MacIntosh argues that 90-day air emissions are an adequate proxy for dust and soil lead ingestion because air lead is deposited in soil and dust. Ex. J, MacIntosh 8/5/20 Dep. at 48:8-12. Dr. MacIntosh purposefully ignores the fact that a sizeable and significant "lead reservoir" exists in the La Oroya area attributable to pre-DRP historical operations of the Complex, and that this reservoir continues to impact the local community. Ex. P, Connor Rep. at 92. Indeed, a 2009 study for the Peruvian government found children in affected communities had as much as a 96% probability of having "blood lead above 10 µg/dL based solely on exposure to contaminated soils." Ex. Q, Hamilton (2009). Yet, Dr. MacIntosh admits that he has not performed any analysis to determine the extent to which this historical lead impacted Plaintiffs (Ex. J, MacIntosh 8/5/20 Dep. at 105:10-21) and, thus, offers no support for his assumptions beyond his own inadmissible *ipse dixit*. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Despite Dr. MacIntosh's baseless assertions to the contrary, abundant data regarding lead in dust and soil was available and, thus, he could have performed a more robust and reliable analysis using a biokinetic model. Since Dr. MacIntosh chose to use an inferior single-factor slope regression model, his model is unreliable. *Bowen*, 906 A.2d at 797.

b. Dr. MacIntosh's model shows that contemporary air emissions are a poor predictor of BLLs

Dr. MacIntosh's predictive model generates a range of predicted BLLs for each individual, with an "upper bound" and "lower bound" estimate. Ex. C, MacIntosh 6/10/19 Rep. at 24. For each Plaintiff, he offers a wide range of possible predicted BLLs—at any point in time, the

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estimated BLL could be anywhere within a range of 40 points or more.[8] *Id.* For example, the modeled BLL range for A.T.M.C. at age 5 goes from 0.2 all the way to 38.9 µg/dL. Ex. B, MacIntosh 05/01/2019 Rep. Table 9.3. As Defendants' expert, Dr. Bowers, explained, this wide range "hampers any use of the model to make predictions for groups, let alone individuals." Ex. M, Bowers Rep. at 12. Similarly, the predicted BLLs diverge significantly from measured BLLs. For example, under Dr. MacIntosh's model Plaintiff S.A.C.O.'s predicted central value BLL was 29.3 µg/dL at 2 years old, 26.1 µg/dL at 5 years old, and 30.2 µg/dL at 7 years old (Ex. C, MacIntosh 6/10/19 Rep. at 24), but her single measured result at age 10 was 3.6 µg/dL. Ex. M, Bowers Rep. at 18. As Dr. Bowers explains, "[i]t is highly unlikely that a child's blood lead level would have ranged from 26 to 30 µg/dL between ages 2 and 7 and then decreased to 3.6 µg/dL only 3 years later." *Id.* Such a decrease of BLL would suggest that blood lead has a half-life of 11.7 months, which is a fraction of both of Dr. MacIntosh's estimates of blood lead half-life. *Id.*; Ex. E, MacIntosh 6/22/20 Rep. at 23.

Third, under generally accepted statistical principles, Dr. MacIntosh's model demonstrates a very low correlation between air lead and blood lead. The "R-squared" value is a measure of correlation between two variables, here BLL and air lead concentration. Ex. N, Rouhani Rep. at 8. The R-squared demonstrates how much of the variation in BLLs can be attributed to changes in air lead, as opposed to other factors. *Id.* In other words, a high R-squared value (up to 1.0) would indicate a strong correlation between individual BLL and air lead emissions. However, his predictive model has an R-squared value of 0.23, which means that nearly 80% of the variability

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[8] Dr. MacIntosh has offered multiple versions of this model with different results, but he has refused to confirm which one of these versions, in his opinion, provides a better estimate of Plaintiffs' BLLs. Ex. J, MacIntosh 8/5/20 Dep. at 28:5–16. Thus, he has injected even more uncertainty into what was already a very uncertain estimate to begin with.

in BLLs is caused by factors other than air lead, such as lead-contaminated soil, dust, and adobe housing. Ex. N, Rouhani Rep. at 9. Therefore, Dr. MacIntosh's own model shows that other factors have more significant impact on individual BLLs than air lead. Dr. MacIntosh's model itself proves that it is an unreliable methodology to attempt to predict blood lead levels.

c.   Dr. MacIntosh made numerous errors in his model

Dr. MacIntosh made many other errors. For example, Dr. MacIntosh included hundreds of duplicate values of blood lead results in his initial analyses. The duplicate values were primarily for La Oroya Antigua and La Oroya Nueva, which consistently had the highest results. Ex. J, MacIntosh 8/5/20 Dep. at 62:17–20. Thus, Dr. MacIntosh's model predicted higher blood lead levels than it otherwise would. Dr. MacIntosh later offered a supplemental report removing some of these duplicated values, but also argued that the failure to de-dupe the data was immaterial. Ex. G, MacIntosh 12/01/20 Rep. at 1. This assertion is contrary to his earlier testimony, where he explained (before he learned of the duplicate data) that he had intended to remove duplicates from the dataset. Ex. J, MacIntosh 8/5/20 Dep. at 63:4–10. He stated it was important to his analysis for every value to "represent a unique individual measurement" because including duplicates would "be reinforcing the information represented by that record" and potentially skew the results of his analysis. *Id.* at 63:11–22, 68:12-70:9. Dr. MacIntosh's computer code, however, did not eliminate all the duplicate values. *See, e.g.*, *id.* at 64:21–65:19, 67:5–68:11. Dr. MacIntosh failed to review the final data used in his models to confirm that his computer code had functioned as intended. It was only after Defendants' counsel showed him the duplicates that he admitted that he would need to "redo the analysis to" determine the impact of the duplication on his models. *Id.* at 68:18–69:8.

B.   Dr. MacIntosh's Allocation Model Is Unreliable and Should Be Excluded

Dr. MacIntosh's allocation model (Fig. 9.7) purportedly estimates "the portion of the plaintiffs' blood lead levels that to a reasonable degree of scientific certainty can be attributed to

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the period when Defendants operated CMLO, October 1997 - June 2009." MacIntosh 6/10/19 Rep. at 25. He does this by estimating how BLLs would have differed if the Complex had stopped operating in 1997 and assigning the difference between his estimates and observations to DRP. Ex. M, Bowers Rpt. at 19; Ex. C, MacIntosh 6/10/19 Rep. at 25-34. This model is dependent on his estimates of background BLLs and half-life (decay rate) of lead. Both are deeply flawed.

1.   Dr. MacIntosh's methodology in calculating background blood lead levels is unreliable

Lead has been ubiquitous in the environment of La Oroya for decades before DRP took over operations at the Complex. Thus, only a portion of the lead present in the area can be attributed to DRP. Any causation opinion must account for the background blood lead levels in La Oroya, *i.e.*, Plaintiffs' BLLs absent any lead emissions from DRP. *See, e.g., LaBauve v. Olin Corp.*, 231 F.R.D. 632, 646 & 646 n.26 (S.D. Ala. 2005) (holding that "it is necessary to place [test results] in context by comparing them to background, or reference, [] values… [T]he data … has meaning vis a vis [defendant's] activities only if compared to the appropriate background level"); *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, 131 F. Supp. 3d 352, 399 (W.D. Pa. 2015) ("Plaintiffs still must demonstrate that they … inhaled uranium from the [defendant's] plant in excess of normal background radiation amounts. Otherwise, they cannot demonstrate causation."). Failure to use a reliable methodology to estimate background levels is ground for exclusion. *Jones v. Novartis Pharma. Corp.*, 235 F. Supp. 3d 1244, 1280 (N.D. Ala. 2017) ("an *unreliable* application of a background risk methodology leads to the same result as a failure to consider the background risk at all: the expert's opinion will be excluded.") (emphasis in original).

Dr. MacIntosh had no discernible methodology in estimating the background BLL. First, Dr. MacIntosh relied on various studies in Peru both before and after the leaded gasoline ban. He estimated the pre-ban BLL in La Oroya to be 5 µg/dL. Ex. C, MacIntosh 6/10/19 Rep. at 27. He

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admitted that, rather than using any kind of scientific or mathematical process, he merely compared the average BLLs found in two studies (Naeher (2003) and (2004)) and picked a number roughly in the middle of those two averages, without really analyzing the data underlying those averages. Ex. I, MacIntosh 5/14/19 Dep. at 195:25-196:9. Naeher (2004) provided an average BLL that combined the results from teenagers, older children, and young children. Ex. M, Bowers Rep. at 21. As young children typically have higher BLLs, the 3 µg/dL average found by Naeher (2004) for all age groups combined is likely lower than the BLL for the young children in the study. For the background BLL after the leaded gasoline ban, Dr. MacIntosh relies on Guillen-Mendoza (2013), which found an average BLL of 2 µg/dL. Ex. C, MacIntosh 6/10/19 Rep. at 27. But that study looks at infant *cord blood levels* which corresponds to the BLLs of the mothers, who, as adults, have lower BLLs than children in the community. Ex. M, Bowers Rep. at 22. Thus, the 2 µg/dL average BLL reported by Guillen-Mendoza is lower than the BLLs for young children. Dr. MacIntosh acknowledged this limitation of the study (Ex. I, MacIntosh 5/14/19 Dep. at 197:24-198:13), but failed to account for this limitation in his report or when designing his model. Further, Dr. MacIntosh mentions but does not consider the Ramirez (1997) study, which reported that in 1994-95, the average BLL for adults in La Oroya was 34.8 µg/dL. Ex. M, Bowers Rep. at 15. As discussed above, children's BLLs are usually higher, peaking around ages 2-3. Here, again, Dr. MacIntosh cherry-picks the data, electing to completely ignore actual data showing that the pre-DRP BLLs were much higher than his estimates. Dr. MacIntosh's own assumptions and models indicate that he has significantly underestimated background BLLs for La Oroya residents.

Notably, Dr. MacIntosh's models show BLLs that are much higher than his estimates of background BLLs. While Dr. MacIntosh opines that background BLLs for La Oroya were 5 µg/dL before the leaded gas ban and 2 µg/dL after, his community model shows the average BLL at zero

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air emissions to be 13 µg/dL, while his predictive model has that level at close to 25 µg/dL. Ex. C, MacIntosh 6/10/19 Rep. at 21, 22 (showing y-intercepts at 13 and 25 µg/dL for Figs. 9.3 and 9.4, respectively). When asked during his deposition whether this evidence suggested that background BLLs were actually higher than he estimated for the purposes of his allocation model, Dr. MacIntosh conceded that this was "a potential interpretation" and "may even be the right interpretation." Ex. I, MacIntosh 5/14/19 Dep. at 165:1-23.

When faced with these criticisms, Dr. MacIntosh denied the importance of background BLLs to his allocation determination. Ex. I, MacIntosh 5/14/19 Dep. at 216:23–25 ("the background turns out not to be a very important factor in this analysis anyway"). He offered no support for this statement. Nonetheless, background rates are crucial to a determination of causation. Without a reliable estimate of background, it is impossible, from both a scientific and legal perspective, to ascertain the extent to which a defendant has caused a harmful exposure. Dr. MacIntosh's failure to reliably estimate background blood lead levels for children in La Oroya renders his allocation opinion unreliable not only because a reliable calculation of background levels is necessary for any causation opinion in an exposure case, but also because his blood lead half-life estimates hinge on these background estimates.

2.   Dr. MacIntosh's blood lead decay rate is unreliable

As part of his allocation model, Dr. MacIntosh purports to estimate the decay rate for blood lead in the body for residents of La Oroya. His allocation model assumes that, had DRP never operated the Complex, BLLs would have naturally decreased in accordance with the half-life of lead in the body.[9] He opines that the difference between the half-life/decay rate from his model

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[9] The half-life of a substance is the amount of time required for the concentration of a substance to decrease by half. Ex. M, Bowers Rep. at 19.

and his predicted BLLs is the portion of BLLs that is attributable to DRP's operations.

Dr. MacIntosh initially estimated blood lead half-life at 55 months, based on three studies, Manton (2000), von Lindern (2003), and Hilts (2003). Ex. C, MacIntosh 6/10/19 Rep. at 28. However, each of these studies had limitations that Dr. MacIntosh did not consider. Ex. M, Bowers Rep. at 22-23. The Manton study is completely inapplicable to this case as the subjects of the study were removed from the exposure source. *Id*. The von Lindern and Hilts studies similarly cannot support Dr. MacIntosh's opinions. He relies on those studies to "characterize[e] the amount by which blood lead in children of a smelter impacted community changes over time" and, specifically, in situations where "the smelter's emissions cease or decrease substantially, and … the residential environment, [both] outdoors [and] indoors, is not cleaned … [or] remediated." Ex. I, MacIntosh 5/14/19 Dep. at 203:3-23; *see also* Ex. C, MacIntosh 6/10/19 Rep. at 28. However, contrary to Dr. MacIntosh's representation, the von Lindern study did involve ongoing lead remediation in the community. Ex. M, Bowers Rep. at 24; Ex. P, Connor Rep. at 168-69. When presented with this fact at deposition, Dr. MacIntosh conceded that he "didn't consider that point." Ex. I, MacIntosh 5/14/19 Dep. at 204:17-25. The applicability of the Hilts study is limited by the fact that background blood levels in the U.S. were also decreasing over the time period of the study, which Dr. MacIntosh does not correct for. Ex. M, Bowers Rep. at 25.

When Defendants pointed out this weakness in his model, Dr. MacIntosh recalculated the blood lead half-life using newer blood lead data, arriving at a blood lead half-life of 89 months—almost three years longer than his original estimate. Ex. C, MacIntosh 6/22/20 Rep. at 23. In what is a recurring theme for Dr. MacIntosh's opinions in this litigation, Dr. MacIntosh does not state which of these rates he thinks is correct; instead, he claims that he "like[s]" both. Ex. J, MacIntosh 8/5/20 Dep. at 128:15–129:12. Under Dr. MacIntosh's original 55-month half-life, and even

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assuming no new exposures to historical lead emissions, background BLLs could not have dropped

to 5 µg/dL by 2004, as Dr. MacIntosh estimates, and, instead, would have likely been around 8

µg/dL. Under Dr. MacIntosh's updated 89-month half-life, the background BLLs would have been

around 13 µg/dL.

Dr. MacIntosh also greatly accelerates the decay rate between 2001-2002 for La Oroya by

arguing that DRP's Hygiene and Environmental Health Program would somehow only remove

historical lead dust. Ex. C, MacIntosh 6/10/19 Rep. at 32-33. His model leads to the illogical

conclusion that as background BLLs dropped as a result of these efforts, DRP's contribution to

resident BLLs increased. *Id.* at 34. In other words, Dr. MacIntosh assumes that DRP's efforts to

reduce lead dust in the community somehow only targeted lead dust left by historical operations

while having no effect on lead dust deposited due to the contemporary operations of the Complex.

These efforts by DRP did not involve soil remediation, so the lead reservoir remained and

continued to re-contaminate the area. "Following this approach, if DRP had done nothing to

address BLL, by Dr. MacIntosh's estimation, its liability for BLL would be much lower. The

absurdity of this result underscores the unsound nature of Dr. MacIntosh's analysis." Ex. P, Connor

Rep. at 170.

3. The allocation model does not and cannot predict DRP's contribution to each individual Plaintiff's blood lead levels

This model does not (and cannot) show DRP's alleged contribution to any given Plaintiff's

BLL at a particular point in time. Ex. I, MacIntosh 5/14/19 Dep. at 190:14–20 ("I just focused on

the average. Not an individual child, hypothetical or real, just focused on the average."). Instead,

Dr. MacIntosh asserts that "[t]he likely portions of blood lead levels attributable to operations of

CMLO after October 1997 … are approximately equal for each Plaintiff." Ex. C, MacIntosh

6/10/19 Rep. at 4. However, Dr. MacIntosh provides no support for this opinion. Even assuming

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that such an allocation were possible, the portion of each Plaintiff's BLL that could be attributed

to the Complex should vary for myriad reasons, such as distance from the Complex, Plaintiffs'

ages at each relevant point in time, their time outdoors, ventilation in their homes, the construction

materials of their homes, and a variety of other factors that would impact each Plaintiff's lead

exposure. Dr. MacIntosh's assumption that the portion of each Plaintiff's BLL attributable to the

Complex would be approximately equal is baseless and erroneous.[10]

4. Dr. MacIntosh improperly conflates individual and community blood lead half-lives

Dr. MacIntosh asserts without support that DRP's contribution to each individual

Plaintiff's BLL is "approximately equal." Ex. C, MacIntosh 6/10/19 Rep. at 4. He appears to base

this conclusion on the assumption that community blood lead half-lives can be attributed to

individuals. However, this is contrary to generally accepted exposure assessment principles. In

fact, Dr. MacIntosh acknowledged in one of his depositions that determining individual blood lead

half-lives requires more data than would be needed for determining community BLLs.

Specifically, when discussing his choice to use the community model as the basis for the allocation

model rather than the predictive model, Dr. MacIntosh stated the community model "was more

appropriate here" because to use the individual BLLs, " we would need to do the analysis for

different ages" and "the information that we have on the half-lives is not specific to any age." Ex.

J, MacIntosh 8/5/20 Dep. at 108:20–109:13.

Thus, per Dr. MacIntosh's own admission, predicted community blood lead half-lives

cannot be extrapolated to individuals and, therefore, his allocation model cannot be used to

determine the percentage of each Plaintiffs' BLLs attributable to emissions from the Complex

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[10] Plaintiffs' expert Howard Hu opines that the attributable fraction of BLL would not be the same and attempted to provide the fractions for each Plaintiff, which varied widely.

during DRP's operation.

C.   It is unclear which version Dr. MacIntosh's models he believes are correct

Dr. MacIntosh has provided *eight* reports in total, most of which he submitted to correct errors pointed out to him by Defendants. He has offered several versions of his predictive model and different estimated BLLs for Plaintiffs. It is now unclear which of the various versions Dr. MacIntosh actually believes to be the most accurate. In fact, Dr. MacIntosh has refused to acknowledge whether any of these data sets may is more accurate than another. Ex. J, MacIntosh 8/5/20 Dep. at 28:5–16. Instead, he characterizes the results as "updated values" based on "refinements" to the model. *Id.* at 81:23–82:13, 100:2–5. The changes in his predicted BLLs combined with the wide range of possible BLLs for each Plaintiff render his modeled values completely unusable for the purpose of determining what Plaintiffs' BLLs likely were at any time. And the modeled values are always going to be unreliable when compared with actual, measured blood lead results.

Dr. MacIntosh has also offered multiple versions of his allocation model. While the first version of his allocation model was based on his individual predictive model (Fig. 9.4), in his June 2020 rebuttal report, he offered a new version of the allocation model based on his community model (Fig. 9.3). Ex. J, MacIntosh 8/5/20 Dep. at 85:23-86:1. This change in methodology results in significant changes to the outcomes of his model, but, once again, Dr. MacIntosh fails to identify which version of the model is correct or more accurate. The bottom line is that all versions of all his models are fatally flawed. His testimony should be excluded in its entirety.

IV.   CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court exclude the opinions and testimony of Dr. MacIntosh.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 15th day of November, 2020, a true and correct copy of the foregoing was filed with the Clerk of the Court through the Court's CM/ECF system, which will affect service on all counsel of record by sending a Notice of Electronic Filing.

  /s/ *Geoffrey M. Drake*